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DEC 19 2012

Section 5

510(k) Summary

General Provisions	Submitter Name:	Merit Medical Systems, Inc.
	Address:	1600 West Merit Parkway, South Jordan, UT 84095
General Provisions	Telephone Number:	(801) 208-4349
	Fax Number:	(801) 253-6967
	Contact Person:	Stephanie Erskine
	Registration Number:	1721504
	Correspondent Name:	Merit Medical Ireland Ltd.
General Provisions	Address:	Parkmore Business Park, Galway, Ireland
	Telephone Number:	(353) 91 703 761
	Fax Number:	(353) 91 771 888
	Contact Person:	Mark Mullaney
	Date of Preparation:	December 19 th , 2012
	Registration Number:	9616662
Subject Device	Trade Name:	BasixCOMPAK
	Common/Usual Name:	Inflation Syringe
	Classification Name:	74 MAV Balloon Inflation Syringe
Predicate Device	Trade Name:	Merit Monarch COMPAK Inflation Syringe & Universal Fluid Dispensing
	Classification Name:	74 MAV Balloon Inflation Syringe
	Premarket Notification:	K083523
	Manufacturer:	Merit Medical Systems, Inc.
Classification	Class II	
	21 CFR § 870.1650, 74 MAV	
	Division of Cardiovascular Devices	
Intended Use	The Merit analog inflation syringe is used to inflate and deflate an angioplasty balloon or other interventional device, and to measure the pressure within the balloon	
Device Description	The Merit analog inflation syringe is a single use disposable device capable of generating and monitoring pressure in angioplasty or other similar interventional devices. It is fitted with a threaded plunger assembly with lock/release bar, flexible high pressure extension tube. It is provided with a 510(k)-cleared three way medium pressure stopcock.	

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**Comparison to
Predicate**

The Technological characteristics of the subject Merit analog inflation device are substantially equivalent to those of the predicate, the Merit Monarch COMPAK Inflation Syringe & Universal Fluid Dispensing Device. The significant difference between the devices relate to the pressure gauge display. The Merit analog inflation device has an analog gauge display. The predicate device has a digital display.

**Safety &
Performance
Tests**

No applicable mandatory performance standards or special controls have been established under Section 514 of the Food, Drug and Cosmetic Act for this device. However, a battery of tests was performed according to protocols based on the requirements of industry standards and guidance and the device met the acceptance criteria necessary to demonstrate the safety and efficacy of the device.

Where appropriate, the tests were based on the requirements of the following documents:

- ISO 11135-1:2007 Sterilization of health care products - Ethylene oxide - Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices.
 - ISO 10993-7:2008 - Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals
 - ASTM F1980-07 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.
 - ASTM D4169 - 09 Standard Practice for Performance Testing of Shipping Containers and Systems
 - ISO 10993-1: 2009 Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process, and the FDA Modified ISO 10993 Test Profile FDA Memo G95-1.
 - ISO 594-1:1996 Conical Fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - general requirements
 - ISO 594-2:1998 Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock fittings
-

**Safety &
Performance
Tests**

The following is a list of all significant testing that has been successfully completed for this device:

- Functional Test (Fluid and Air)
 - Torqueability Test
 - Tensile Test
 - Thermal Shock – Leak Test
 - Transportation Simulation
 - Gauge Responsiveness Test
 - Volumetric Comparison Test
 - Greening Effect
 - Vacuum Capability Test
 - Gauge Accuracy and Precision
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**Summary of
Substantial
Equivalence**

Based on the indications for use, design, safety, and performance testing, the subject Merit analog inflation device meets the requirements that are considered essential for its intended use and is substantially equivalent to the predicate device, the Merit Monarch Inflation Syringe (K083523) manufactured by Merit Medical Systems, Inc. Differences between the devices do not raise any different questions of safety or effectiveness.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Merit Medical Systems, Inc.
c/o Stephanie Erskine
1600 West Merit Parkway
South Jordan, UT 84095

DEC 19 2012

Re: K122321

Trade/Device Name: BasixCOMPAK
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector and Syringe
Regulatory Class: Class II
Product Code: MAV
Dated: November 29, 2012
Received: November 30, 2012

Dear Ms. Erskine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Matthew G. Hillebrenner

for

Bram Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4

Indications for Use Statement

510(k) Number (if known): K122321

Device Name: BasixCOMPAK

Indications for Use:

The Merit analog inflation syringe is used to inflate and deflate an angioplasty balloon or other interventional device, and to measure the pressure within the balloon.

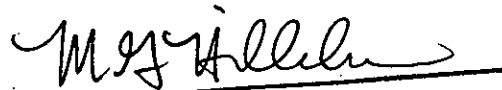
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular Devices

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